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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/578,827	05/24/2000	Philip N. Benfey	5914-078-999	5552

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 01/03/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/578,827

Applicant(s)

BENFEY ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2000 and 19 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 22-25, 27 and 30-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-25, 27 and 30-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                    | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8, 15</u> | 6) <input type="checkbox"/> Other:  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group VII, claims 22-25 and 27, is acknowledged. Claims 1-21, 26 and 28-29 have been cancelled. Claims 30-33 have been newly added. Claims 22-25, 27 and 30-33 are pending and are examined in the instant office action.

### ***Information Disclosure Statement***

2. An initialed and dated copy of Applicant's IDS form 1449, Paper Nos. 8 and 15, is attached to the instant Office action.

### ***Claim Objections***

3. Claim 23 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 23 is dependent on cancelled claim 21. Additionally, claim 23 is drawn to the transgenic plant of claim 21 in which the gene of interest encodes a gene product that confers herbicide, salt, pathogen, or insect resistance, yet the transgenic plant of claim 21 is a genetically engineered plant in which the endogenous *SHORT-ROOT* gene is disrupted or inactivated. It is apparent that claim 23 was meant to depend on a claim other than claim 21.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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5. Claims 22-25, 27 and 32-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

6. The claims are drawn to a transgenic plant containing a gene of interest operatively associated with a *SHORT-ROOT* promoter. The claims are also drawn to isolated nucleic acid molecules that hybridize to SEQ ID NO:4 under high stringency conditions.

7. However, the specification does not set forth what specific structural or physical features are required in the claimed *SHORT-ROOT* promoter contained within the transgenic plant. The specification does not set forth what specific structural or physical features are required in the claimed isolated nucleic acid molecules that hybridize to SEQ ID NO:4 under high stringency conditions. The specification only discloses a single *SHORT-ROOT* promoter of SEQ ID NO:4 that has promoter function in transgenic *Arabidopsis* roots and embryos (pages 66-67 and *Figures 3 and 4*). The identities of the claimed transgenic plants and isolated nucleic acid molecules are uncertain. The structural and physical features of the claimed transgenic plants and isolated nucleic acid molecules cannot be ascertained in the absence of information about the functional activity of the nucleic acid molecules that they comprise. The specification does not disclose whether any nucleic acid molecule other than SEQ ID NO:4 will function as a promoter in a cell or plant.

8. See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), where it states:

"The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent

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pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA ... Accordingly, the specification does not provide a written description of the invention ..."

9. Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed transgenic plants and isolated nucleic acid molecules, and given the high level of unpredictability in this art of defining nucleic acid molecules that would function as promoters, one skilled in the art would not have been in possession of the claimed invention at the time this application was filed.
10. Claims 22-25, 27 and 30-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid sequence of SEQ ID NO:4, and a transgenic *Arabidopsis* plant comprising a gene of interest operatively associated with a *SHORT-ROOT* promoter of SEQ ID NO:4, does not reasonably provide enablement for other promoter sequences, or other plants comprising other promoter sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.
11. The claims are drawn to a transgenic plant comprising a gene of interest operatively associated with a *SHORT-ROOT* promoter. The claims are also drawn to an isolated nucleic acid of SEQ ID NO:4, and to an isolated nucleic acid that hybridizes under stringent conditions to SEQ ID NO:4.
12. The specification only discloses a single *SHORT-ROOT* promoter of SEQ ID NO:4 operatively associated with a GFP reporter gene, and expression of the reporter gene in the stele of roots and hypocotyls (pages 66-67 and *Figures 3 and 4*). The specification does not teach whether any other nucleic acid molecule has promoter function, such as an isolated nucleic acid that hybridizes under stringent conditions to SEQ ID NO:4 that drives the expression of a

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reporter gene. The specification does not teach whether SEQ ID NO:4 has promoter function in shoots. The specification does not teach whether a transgenic plant containing any gene of interest operatively associated with SEQ ID NO:4 is less susceptible to lodging. Furthermore, the specification does not set forth any specific structural characteristics that are critical for the promoter function of the claimed nucleic acid molecules, such as the identification of specific nucleotides in a claimed nucleic acid sequence whose alteration affects promoter activity.

13. Guidance for making and using the claimed invention is necessary for enablement because the ability of a particular nucleic acid sequence to function as a promoter is highly unpredictable on the basis of nucleotide sequence information alone, and because the ability of a particular nucleic acid sequence to function as a promoter in different transgenic plants is also highly unpredictable.

14. Kim et al. teach that various point mutations in the *nos* promoter can alter the level of promoter activity in tobacco (Plant Molecular Biology, 1994, Vol. 24, pages 105-117). Mutation of one or more nucleotides in either of two hexamer motifs significantly decreased the level of *nos* promoter activity (Table 2, page 109).

15. Benfey et al. teach that different combinations of subdomains of the CaMV 35S promoter exhibited different levels of promoter activity (Science, 1990, Vol. 250, pages 959-966, see Table 1, page 963). Benfey et al. also teach that the tissue specificities of subdomains of the CaMV 35S promoter can vary depending on the location of a subdomain within a promoter. Individual promoter subdomains exhibited different patterns of tissue specific expression when used alone, as compared to when used in combination with a different subdomain. (Figure 1, page 960). In addition, particular combinations of subdomains exhibited different patterns of tissue specific expression when transformed into different species of plants (Figure 4, page 963).

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16. Thus the ability of a particular nucleic acid sequence to function as a promoter can vary depending on the mutation of even a single nucleotide in that nucleic acid sequence, the location of that nucleic acid sequence relative to other nucleic acid sequences, and the species of plant into which that nucleic acid sequence is introduced. Because the ability of the claimed DNA fragments to function as promoters is not described by analogy or by example, the claimed invention is not enabled by the specification in the absence of further guidance or example.

17. Given the unpredictability of a particular nucleic acid molecule functioning as a promoter, the absence of guidance in the specification for making and using the claimed transgenic plants and isolated nucleic acid molecules, the lack of working examples, and given the breadth of the claims which encompass any transgenic plant comprising any *SHORT-ROOT* promoter and any isolated nucleic acid molecule that hybridizes under high stringency conditions to SEQ ID NO:4, it would require undue experimentation by one skilled in the art to make and/or use the claimed invention.

18. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

19. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 22 is indefinite in its recitation of the transitional phrase "containing" because the scope of the claim is unclear.

***Claim Rejections - 35 USC § 102***

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

21. Claims 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Bevan et al.

(GenBank Accession No. AL035605, March 4, 1999).

22. The claims are drawn to an isolated nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO:4.

23. Bevan et al. teach an isolated nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO:4.

24. Accordingly, claims 31-33 are anticipated by Bevan et al.

**Remarks**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell can be reached on (703) 308-4310. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and 1 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC  
December 21, 2001

ELIZABETH F. McELWAIN  
PRIMARY EXAMINER  
GROUP 1600

*Elizabeth F. McElwain*